REMARKS

Introductory Comments:

Claims 40-54 were examined in the Office Action under reply. Applicants note with appreciation the apparent withdrawal of the species election requirement as previously withdrawn claims have been stated as being pending and under consideration in the Office Action Summary and on page 2 of the Office Action. Additionally, claims 50 and 51 which were previously withdrawn from consideration are explicitly rejected in the Office Action.

Applicants also acknowledge with appreciation the withdrawal of the previous objection under 35 U.S.C. §132 stated in paragraph 3 of the Office Action mailed July 3, 2000, as well as the rejection under 35 U.S.C. §112, first paragraph stated in paragraph 5 of the same Office Action.

Claims 40-42, 45, 48, 49 and 52-54 were rejected herein under 35 U.S.C. §112, first paragraph and claims 50 and 51 were rejected under 35 U.S.C. §112, second paragraph. These rejections are believed to be overcome by the above amendments and are otherwise traversed for reasons discussed below.

Additionally, applicants note that claims 43 and 44 were not subject to any rejections. However paragraph 9 of the Office Action states that no claim is allowed. Clarification is therefore requested.

Overview of the Above Amendments:

Claims 40, 45 and 48-51 have been canceled without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve their right to pursue these claims again in a related application. Additionally, claims 41, 42, 46, 47, 52 and 54 have been amended to depend from noncanceled claims.

New claims 55-57 have been added and find support throughout the specification at, e.g., page 33, line 9 to page 34, line 26.

Rejections Under 35 U.S.C. §112, First Paragraph:

Claims 40-42, 45, 48, 49 and 52-54 were rejected under 35 U.S.C. §112, first paragraph "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action, page 2. The Office asserts:

> There is no support in the specification as originally filed for the recitation 'wherein the immunogenic peptide does not contain any other sequence corresponding to a hypervariable domain of hepatitis C virus' in the context recited in claim 40.

Office Action, pages 2-3, bridging paragraph. However, applicants respectfully disagree.

In order to comply with the written description requirement, an applicant's specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, i.e., whatever is now claimed. *Vas Cath Inc. v. Mahurkar,* 19 USPQ 1111, 1117 (Fed. Cir. 1991) (cited in MPEP § 2163 and in the Examiner Guidelines on Written Description Requirement). The Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim,* 191 USPQ 90 (CCPA 1976) (cited in MPEP § 2163.04 in the Examiner Guidelines on Written Description Requirement). Determining whether the written description is satisfied requires reading the disclosure in light of the knowledge possessed by those skilled in the art. *In re Alton,* 37 USPQ2d 1578 (Fed. Cir. 1996). Applying these tenets, applicants submit that the Office has failed to carry its burden and that the present claims indeed comply with the written description requirement of 35 U.S.C. §112, first paragraph.

The Office has failed to supply any "evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims," *In re Wertheim,* 191 USPQ 90 (CCPA 1976). In fact, a review of the application as a whole evidences that the application is more than sufficient to convey with reasonable clarity to those skilled in the art that, as of the filing date sought, they were in possession of the invention (here, immunogenic polypeptides with the recited amino acid motif which does not include other HCV hypervariable domain sequences). The application provides polypeptides in the examples which are devoid of such sequences. It is of no consequence that the words "wherein the amino acid sequence motif is the only sequence corresponding to a hypervariable domain of hepatitis C virus" are absent from the specification. Verbatim support for the claims is not required. As explained above, what is required is that one of skill in the art would recognize that applicants' specification encompassed the claimed subject matter. This is certainly true here. It is evident applicants intended to cover molecules as recited. Thus, this rejection is believed to be in error.

Nevertheless, the current claims do not include this recitation. Applicants note that claim 53 which was included in this rejection is an independent claim and the complained of recitation is not found therein. Accordingly, applicants assume this is an inadvertent error and that this claim is actually allowable as no other rejections of claim 53 are present. All claims now depend either directly or ultimately from claim 53. Accordingly, this basis for rejection is believed to be overcome and withdrawal thereof is respectfully requested.

Claim 52 was also rejected under 35 U.S.C. §112, first paragraph, the Office alleging "[t]here is no support in the specification as originally filed for the immunogenic composition of claim 52." Office Action, page 3. The Office argues that the specification discloses a vaccine but not an immunogenic composition and reasons that the terms "vaccine" and "immunogenic composition" are not interchangeable. Office

Action, page 3. However, applicants submit that there is more than adequate support in the application as filed for the term "immunogenic composition." In particular, the application at page 14, lines 1-4 explains that the term "immunogenic" means the ability to elicit a cellular and/or humoral immune response. It is well understood by those of skill in the art that a humoral immune response relates to the production of antibodies. It is true that an antibody response can lead to treatment of a disease. Alternatively, antibodies can be raised for other uses, such as for passive immunization and for diagnostic applications. In fact, the examples in the present application detail immunization of sheep with a peptide spanning the HCV E2HV region in order to produce antibodies for passive immunization. Accordingly, applicants submit that the term "immunogenic composition" is indeed supported. Thus, withdrawal of the rejection of claim 52 is respectfully requested.

Rejections Under 35 U.S.C. §112, Second Paragraph:

Claims 50 and 51 were rejected under 35 U.S.C. §112, second paragraph, as indefinite. The Office asserts that these claims lack antecedent basis in claim 40. Office Action, page 3. Although applicants respectfully disagree, these claims have been canceled in an effort to hasten prosecution. Thus, this basis for rejection has been rendered moot. Withdrawal thereof is respectfully requested.

Request For Interview:

Should the Office decide to maintain the present rejections, applicants request an interview to discuss this and the corresponding applications prior to issuance of the next Office Action.

CONCLUSION

Applicants respectfully submit that the claims are novel and nonobvious over the art and comply with the requirements of 35 U.S.C. §112. Accordingly, allowance is believed to be in order and an early notification to that effect would be appreciated.

Please direct all further communications in this application to:

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Respectfully submitted,

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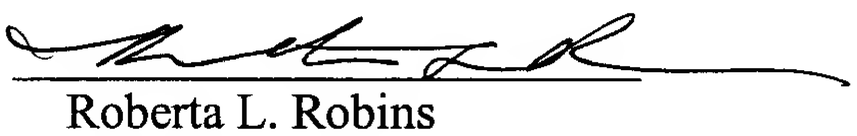
By: 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 41, 42, 46, 47, 52 and 54 have been amended as follows:

41. (Amended) A fusion protein comprising the immunogenic polypeptide of claim [40] 53.

42. (Amended) The immunogenic polypeptide of claim [40] 53 linked to a suitable carrier.

46. (Amended) The immunogenic polypeptide of claim [45] 57 wherein the [amino acid motif] polypeptide is linked to a disulfide/amide-forming agent.

47. (Amended) The immunogenic polypeptide of claim [45] 57 wherein the [amino acid motif] polypeptide is linked to a thio-ether-forming agent.

52. (Amended) An immunogenic composition comprising a pharmaceutically acceptable carrier and the immunogenic polypeptide of claim [40] 53.

54. (Amended) The immunogenic polypeptide of claim [40] 53, wherein

Xaa at position 1 is an amino acid selected from the group consisting of Ala, Ser, Glu, Gln, Gly, His, Thr, Asp, Arg, Lys, Asn, and Val;

Xaa at position 3 is an amino acid selected from the group consisting of Tyr, Gln, Arg, His, Thr, Asn, Ile, Leu, and Ser;

Xaa at position 8 is an amino acid selected from the group consisting of Ala, Gln, Val, Ile, Asn, Thr, Ser, Lys, Glu, Arg, and His;

Xaa at position 14 is an amino acid selected from the group consisting of Asn, Arg, His, Lys, Ala, Tyr, Ser, Phe, Leu, Gln, and Thr;

Xaa at position 16 is an amino acid selected from the group consisting of Phe, Val, Ile, and Leu;

Xaa at position 17 is an amino acid selected from the group consisting of Val, Ala, Thr, Ser, and Pro;

Xaa at position 21 is an amino acid selected from the group consisting of Arg, Ser, Gly, Thr, Asn, Met, Ala, Leu, Thr, Gln, Asp, Lys, and Glu;

Xaa at position 22 is an amino acid selected from the group consisting of Ser, Pro, Leu, Val, His, Arg, Tyr, Gln, Thr, and Ala;

Xaa at position 24 is an amino acid selected from the group consisting of Ala, Ser, and Pro; and

Xaa at position 27 is an amino acid selected from the group consisting of Asn, Asp, Lys, Arg, Thr, and Glu.

Claims 40, 45 and 48-51 have been canceled.

New claims 55-57 have been added:

--55. (New) The immunogenic polypeptide of claim 42, wherein the carrier is diphtheria toxoid.

56. (New) The immunogenic composition of claim 52, wherein the carrier is diphtheria toxoid.

57. (New) The immunogenic polypeptide of claim 54 linked to a suitable carrier.--